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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,928	11/28/2000	Stephen P.A. Fodor	018547036750	9541

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EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,928	FODOR ET AL.	
	Examiner	Art Unit	
	Karlheinz R. Skowronek	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 57-61,63-69,71-82,84-90,92-98,100,101,106-109,111-113,115-120,123-125,129-132,135,136,141-144,149,151,152,154 and 156-172.

Continuation of Disposition of Claims: Claims rejected are 57-61,63-69,71-82,84-90,92-98,100,101,106-109,111-113,115-120,123-125,129-132,135,136,141-144,149,151,152,154 and 156-172.

DETAILED ACTION

Claim Status

Claims 57-61, 63-69, 71-82, 84-90, 92-98, 100-101, 106-109, 111-113, 115-120, 123-125, 129-132, 135-136, 141-144, 149, 151-152,154, and 156-172 are pending.

Claims 73, 78, 80, 86, 88, 94, 108, 111-113, 115, 120, 123, 125, 132, 135-136, and 141-144 are amended.

Claims 102-104 are cancelled.

Claims 163-172 are newly added.

Claims 57-61, 63-69, 71-82, 84-90, 92-98, 100-101, 106-109, 111-113, 115-120, 123-125, 129-132, 135-136, 141-144, 149, 151-152,154, and 156-172 are being examined.

Election/Restrictions

Applicant's election with traverse of species Bi and Bii in the reply filed on 26 October 2006 is acknowledged. The traversal is on the ground(s) that the chemical structure of oligonucleotides and DNA are not different. Species of Bi and Bii will be examined together. The examiner maintains the distinction between species Bi, directed to oligonucleotides, and Biii, directed to peptides. The examiner also maintains the distinction between Bii, directed to nucleic acids, and Biii, directed to peptides

The requirement is still deemed proper and is therefore made FINAL.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Applicant is advised that should claim 151 be found allowable, claim 154 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 77 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

   a. Regarding claim 77, since claim 77 depends from claim 76 which recites the limitation that polymers are nucleic acids and the limitations of claim 76 are read into claim 77, it is therefore unclear how a nucleic acid can also be a polypeptide.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

2. Claims 163-172 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

In the instant case, the claims recite the limitation of "each different polymer is attached to a bead". The only reference to beads in the specification is the sentence on p. 11, lines 14-17. This reference to beads does not indicate that polymers are attached to the beads. One of ordinary skill would not know that the polymers are attached to the beads of lines 14-17, but would rather assume that the beads are utilized in some form during synthesis and are only important during synthesis. It appears from the context of lines preceding the reference to the beads that the beads are actually employed to physically separate the synthesis regions (p. 11, lines 9-14). A bead on the surface of the substrate is also a raised region (line 13). Thus, the recitation of " each polymer is attached to a bead" is new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 57-59, 65-67, and 73-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Shack et al (Journal of Histochemistry and Cytochemistry, Vol. 27, No. 1, p. 153-159, 1979).

The claims are directed to a computer program, computer software and a system for acquiring data from an array of polymers by: scanning, in which a scan stage is moved, a plurality of diverse polymers, each a polymer having a different sequence and localized in an area of less than 25,000 μm^2 and a density of more than 400 polymers/cm^2; receiving pixel data; collecting pixel data; storing the data in file and displaying the data.

Shack et al. describe a computerized system in which a the stage of a microscope is moved in an automated manner (abstract, lines 5-6) to image epithelial cells attached to a glass microscope slide (abstract lines 1-4), reading on an array of polymers. Shack et al teach that epithelial cells vary in size between 40 and 100 μm in diameter which corresponds to an area of 7850 μm^2 at the maximum cell diameter (p. 154, col. 1, para. 4, lines 4-5). Since each cell would be localized to a distinct location of the microscope slide, the cells read on the limitations of localized areas less than 25,000 μm^2. Furthermore, since cells are composed of polymers, the cells also read on the limitations of polymers and on the polymer densities of more than 400 polymers per cm^2. Shack et al teach receiving of the pixel data from the sample on the array as collecting data at a spatial sampling distance of 0.5 μm which is being read as teach the size of a single pixel using a photomultiplier tube (p. 157, col. 2, para. 3, line 2). The

light intensity obtained by the photomultiplier tube is collected (p. 157, col. 1, para. 2, line1), stored (p.157, col. 2, para. 4, lines 9-11) and displayed (p.154, col. 2, para.3, line2).

4. Claims 57, 65,73, 78, 86, 94,108,120, 132, and 144 are rejected under 35 U.S.C. 102(a) as being anticipated by Southern (WO 1989/10977).

The claims are directed to computer programs, computer softwares, systems for acquiring data from a polymer array using a scanner to scan a plurality of diverse polymers in an array format on a substrate, each polymer having a different sequence and being localized in an area of $2.5x10^5$ microns^2 with density of 400 polymers per cm^2, the data being in the form of pixels and being collected.

Southern et al teach a system, software and program of acquiring data (p. 14, lines 17-18 and 27-29) from DNA arrays (p. 11, lines 10-14) on a microscope slide substrate (p. 14, lines 32-33). The array of distinct polymers of Southern et al is formed through the attachment of polymers to a glass substrate, in localized areas of 100 microns^2. Southern teach that $3x10^{-12}$ micromol of DNA occupy the area of 100 microns^2 (p. 12, lines 30-32), which equates to $18x\ 10^5$ molecules/100 μm^2. The Microscope slide of Southern et al has dimensions of 7.6cm x 2.6cm x 0.1cm (76mm x 26mm x 1mm) (p. 14, 32-33) on which the array is formed thereby allow for an array of 7 cm x 2 cm which would contain $1x\ 10^6$ distinct polymers per cm^2. Southern et al teach the acquisition and collection of data from autoradiographic images (p. 14, lines17-29) created by nucleic acids hybridized to the microscope arrays (p. 17, lines 20-21). Thus,

the apparatus and program/software for the acquisition of data from array of southern anticipates the instantly presented claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 57-60, 63-68, 71-76, 78-82, 84-90, 92-98, 100,101, 108, 113-120, 123-125, 129-132, 135-136, 141-144, 149, 151-152, and 156-162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southern et al (WO 1989/10977), in view of Rushbrooke et al (WO 1988/04045).

The claims are directed to computer programs, computer softwares, and systems for performing methods comprising: inputting a plurality of data indicative of binding

between polymers on a substrate and ligands in a sample solution in which the data are signal intensity versus position on the substrate and the polymers on the substrate are further localized to discreet areas that smaller than 2.5x105 microns^2; creating a image of the signal intensity versus position; and displaying the image to a user.

Southern et al teaches the construction, use, and analysis of arrays of nucleic acid polymers immobilized on a glass microscope slide substrate. The immobilized polymers of Southern et al are immobilized in areas of less than 2.5x105 μm^2, specifically 100μm^2 cells (p. 11, lines 25-26). The number of molecules located in the localized area is $3x10^{-12}$ μmol per 100μm^2 (p. 12, lines 31-32), that is $18x\ 10^5$ molecules/100 μm^2 which is greater than the instantly claimed polymer density 10, 000 polymers per cm^2. Example 4 of southern, demonstrates the binding of ligand in solution (p. 20, line 3) to the polymers immobilized on the substrate (p. 20, line 3-4) to generate data indicative of binding (p. 20, lines 10-12). Southern et al. suggest that fluorescence signal (p. 14, lines 13-15) can also be used and that the process of data acquisition and analysis could be auto mated by computer systems programs and software (p. 14, lines 17-18 and 27-29).

Southern et al do not teach a system computer program or computer software used for inputting data from an array of nucleic acids based photon counts from fluorecscence intensity.

However, Southern et al motivates one of skill in the art to combine the methods use and detection of immobilized polymers with a computerized scanning system (p. 14, lines 17-29).

Rushbrooke et al describe computer program, computer software and system in which input data relating to signal intensity versus position (p. 5, lines 16-20) are used to create an image of the signal intensity versus position (i.e. scanning) (p. 6, lines 21-24) that is displayed to a user (p. 6, lines 8-10). The system of Rushbrooke et al utilizes a microscope to input data (p.5, line 3). Rushbrooke et al teach the signal is fluorescence intensity (p. 4, lines 10-12) based on photon counts (p. 3, line 3).

It would have been obvious to one of ordinary skill in the art to combine the system and software for signal data acquisition and analysis of Rushbrooke et al with microscope slide microarrays of Southern et al because Rushbrooke et al teach a high sensitivity optical imaging system allowing the detection of low light levels for measurement of very small quantities of light emitted by diagnostic samples (p. 1, lines 1-6) and applicability of their invention to fluorescence microscopy and x-ray digital imaging (p. 4, lines 10-16).

One would have had a reasonable expectation of success and been motivated to do so by Southern et al who teach a digitizing scanner that can scan a matrix of several million cells in a few minutes (p. 14, lines 25-27).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Obviousness Double Patenting

6. Claims 57-60, 63-68, 71-76, 78-82, 84-90, 92-98, 100,101, 108, 113-120, 123-125, 129-132, 135-136, 141-144, 149, 151-152, and 156-162 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-131 of U.S. Patent No. 6,403,320 (hereafter the '320 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '320 patent claims an apparatus (reading on the instantly claimed system) and a method which is carried out by a computer (reading on both the instantly claimed software and program) comprising the limitation of the instant application. Furthermore the specific limitations of the instantly claimed system, program, and software claims are also specifically recited in the claims of the '320 patent. For example, reading on the program and software claims of the instant application reciting a localized area of smaller than $2.5x10^5$ μm^2, the '320 patent recites nucleic acids in claim 1 that are localized in an area of 10^{-2} cm^2 which is 10^4 μm^2 and directly claimed in claim 4 locations having less than 10,000 square microns. One of ordinary skill will readily recognize the CCD detector of the '320 patent intrinsically registers pixel data from the

array and that data is collected and stored in a data storage system (reading on a file). Further limitations of the claims in the '320 patent recite the limitations of displaying the data on a video display (cl. 59).

7. Claims 73-74,76, 94-98, 144,149, are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 11-17 of U.S. Patent No. 6,403,957 (hereafter the '957 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application recite limitations that are obviated by the claims of the '957 patent. For example, the claims of the '957 patent recite the limitations of scanning a substrate comprising a plurality of different poly nucleotides, movement of a scan stage, receiving image data, collecting and storing image data.

8. Claim 73, 94, and 144 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,545,264. Although the conflicting claims are not identical, they are not patentably distinct from each other because the system claimed in the '364 patent makes the limitation of the instant claims obvious. For example, the claims of the '264 patent recite the limitations of receiving image data from a polymer array, a moving scan stage, and image collection.

Provisional Obviousness Double Patenting

9. Claims 57-60, 63-68, 71-76, 78-82, 84-90, 92-98, 100,101, 108, 113-120, 123-125, 129-132, 135-136, 141-144, 149, 151-152, and 156-162 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable

over claims 1-62 of copending Application No. 10/190, 951. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '951 application recite similar limitations as in the instant application. For example, claims 1-20 are directed to a method (interpreted to read on software and programs as being automated methods) and to a system. The method claimed in the '951 application receives and collects intensity data from a polynucleotide array and display the data.

10. Claim 57, 59-60, 65,67-68, 73, 75-77, 78-82, 86-90, 94-98, 108,113, 117, 120, 125, 129, 132, 141, 144, 149, and 156-162 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-34 of copending Application No. 10/219,882. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '882 application recite similar limitations as in the instant application. For example, claims 32-34 of the '882 application are directed to a program product (reading on software and a program) and to a system. The programs receive and collect intensity data from a polynucleotide array and display the data.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karlheinz R. Skowronek/
KRS

MICHAEL BORIN, PH.D
PRIMARY EXAMINER